

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and the following remarks.

I. Status of the Claims

With this submission, claims 1, 10, 12, 16, 18, and 19 are currently amended. Claims 23 and 24 are newly added.

Claims 2-8 and 22 are canceled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicant reserves the right to pursue the subject matter of canceled claims in subsequent applications. These amendments do not introduce any new matter into the application and their entry is respectfully requested.

Upon entry of this amendment, claims 1, 9-21 and 23-24 will remain pending.

II. The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action, at page 2, rejects claims 1, 3-6 and 9-21 as allegedly failing to comply with the definiteness requirement. Solely in the interest of advancing prosecution, Applicant removed the term “multiple unsaturated triglycerides” as used in the instant claims. Accordingly, Applicant believes the rejection is moot. Reconsideration and withdrawal of this rejection is respectfully requested.

III. The Rejections Under 35 U.S.C. § 103(a)

A. The Rejection Over Alexander in View of Horrobin

The Office Action rejects claims 1, 3, 6, 9, 14-19 and 21 under 35 U.S.C. § 103 as allegedly unpatentable over Alexander (EP 0691079 A2; 1996) in light of Horrobin (US 6,479,544). On pages 3-8 of the Official Action, the Office takes the view that the claims are obvious in light of Alexander and Horrobin. The Office admits that Alexander fails to teach (1) the amount of saturated long-chain triglycerides of 6% at most; (2) the amount of fat

phase versus aqueous phase; (3) the amount of zinc and/or chromium; or (4) the inclusion of eicosapentaen and/or docosahexaen acid. (Office Action, page 4) Nevertheless, the Office argues that the composition would have been within the purview of one of ordinary skill in the art or obvious in light of Horrobin. Applicant respectfully traverses the rejection.

1. Alexander and/or Horrobin Fail to Teach Each and Every Element of the Claimed Invention

When determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, “*there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.*” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)). The failure of an asserted combination to teach or suggest **each and every feature of a claim remains fatal** to an obviousness rejection under 35 U.S.C. § 103 and MPEP 2143.03.

In an effort to advance prosecution of this application and without acquiescing to the propriety of this rejection, Applicant has amended the claims to include the term “10 to 30% triglycerides of octanoic and/or decanoic acid.” None of the cited references teach this limitation. Furthermore, Applicant describes in Section III(A)(2) below that the percentages of these medium chain triglycerides exhibits unexpectedly good results. Accordingly, Applicant believes this amendment renders the rejection moot.

2. Unexpected Results

Alexander merely teaches that the long-chain triglycerides can be provided as particular plant oils, and fails to teach or suggest a conversion product which might result in a mixture of fatty acids containing the particular amounts of DHA and EPA claimed in the present application. Even assuming, *arguendo*, that the metabolized products of the composition disclosed by the prior art are relevant, after considering all of the prior art,

including Horrobin, there is no predictability to one of skill in the art regarding the metabolized products resulting from the conversion of Alexander's composition.

When one considers the obviousness of a combination of known elements, the operative question is "whether the improvement [in combining elements found in the prior art] is more than the predictable use of [the] elements according to their established functions." MPEP § 2141(I), citing *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). "While obviousness does not require absolute predictability, *at least some degree of predictability is required.*" MPEP § 2143.02(II) (emphasis added).

Applicant attaches as Exhibit A a new study describing clinical trials using the subject-matter of the instant application. The aim of this double-blind study was to establish whether the substitution with a fat spread containing 6 g/d MCT (MCT 30% is a product according to the invention) would have any effect on clinically significant parameters in overweight diabetic patients. The patient cohort was randomly assigned to receive the product of the invention or equivalent product having a reduced amount of 2 g/d MCT (MCT 6% as the control). Patients were asked to consume 2 x 15 g/d of the fat spread for 12 weeks as a substitute for their usual dietary spread. Moreover, patients were instructed to maintain their common diet and physical activity level. In other words, the patients were not required to reduce caloric intake or to participate in physical activity.

The results of this study show a statistically significant reduction in the waist circumference (WC) of patients using the MCT 30%. One of skill in the art would not have expected such a dramatic result when using the composition described in the clinical study.

It is well known that *diabetes mellitus* is a condition which substantially depends on dietary habits and level of physical activity. Although diabetic patients are routinely advised to adopt a healthy diet and to exercise, it is well-established that non-compliance in this patient population is substantial. Specifically, there is a tendency to revert to medication (administration of more insulin) rather than to change dietary habits or exercise.

In light of the above, there is a need for a dietary product, such as fat spread or cooking oil which may be used as a simple substitute for diabetic patients, and which will

exert a beneficial effect in these patients, even under the premises that the patient may not adhere to the recommended diet. This is exactly what the present invention has achieved as shown by the surprising results of the clinical trial.

3. If Modified Horrobin's Principle of Operation Would Change

According to MPEP 2143.01 Section VI, "if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." Citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Horrobin is directed to the use of eicosapentaenoic acid (EPA) in combination with arachidonic acid (AA). This combination is key because "contrary to the general expert opinion, it has now been found that AA is highly desirable rather than undesirable." Thus the modification of Horrobin to a composition that does not require AA would change the principle of operation of Horrobin. Accordingly, Horrobin cannot be used to render the instant claims obvious.

For at least the reasons stated above, the rejection of the claims under 35 U.S.C. § 103(a) is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

B. The Rejection Over Alexander in Light of Horrobin in View of Madigan, Heine and The Merck Index

The Office also rejects claims 1, 3-6, 9-10 and 14-21 over Alexander in light of Horrobin, in view of Madigan ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care* 23:1472-1477; 2000), Heine ("Linoleic-Acid-Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr*, 49(3):448-456; 1989, Abstract Only) and the Merck Index ("Citric Acid", Monograph 2328, 1989; page 363). Applicant respectfully traverses this ground of rejection.

The additional references, Madigan, Heine and the Merck Index, do not remedy the deficiencies of Alexander and Horrobin demonstrated above, as none of these references

clarifies the metabolic conversion of acids or discloses a composition comprising 10 to 30% triglycerides of octanoic and/or decanoic acid, as claimed in the present application.

Accordingly, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

C. The Rejection Over Alexander in Light of Brenna and Further in View of Bell and Mendy

The Office also rejects claims 1, 3-6, 9, 11-19 and 21 over Alexander in light of Brenna, and further in view of Bell (WO 97/38593), and Mendy (US Patent No. 4,407,821). Applicant respectfully traverses this ground of rejection.

The additional references, Bell and Mendy, do not remedy the deficiencies of Alexander and Brenna demonstrated above, as none of these references clarifies the metabolic conversion of acids or discloses a composition comprising 10 to 30% triglycerides of octanoic and/or decanoic acid, as claimed in the present application. Accordingly, the rejection is improper.

Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

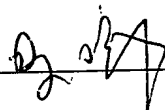
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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EXHIBIT A